REMARKS

Claim rejection - 35 U.S.C. § 103(a)

Claims 1-10 are pending, and none of claims 1-10 is amended herein. Claims 1-10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over US 3,442,686 to Jones ("Jones") in view of US 3,967,728 to Gordon et al. ("Gordon") and further in view of US 4,585,666 to Lambert ("Lambert").

Applicants respectfully submit that a *prima facie* case of obviousness has not been established for the following reasons:

- the combination of references does not suggest or result in the claimed invention, and
- the combination of references is based on impermissible hindsight.

I. The combination of references does not suggest or result in the claimed invention.

The primary reference to Jones is cited for its disclosure of a method of using a laminate as a barrier material against gases. The method allegedly employs the same laminate as recited in claim 1. However, at page 3, lines 11-16, of the Office Action, the Examiner states that the primary reference to Jones fails to teach the following recited features of the claimed invention:

(1) the specific type of gas such as ethylene oxide

(2) a package containing a medical instrument having a hydrophilic outer surface coating;

(3) a sealed container containing a sterile wetting fluid for wetting the hydrophilic coating of the instrument;

(4) the laminate is substantially impermeable to ethylene oxide gas; and

(5) exposing the package to ethylene oxide gas.

Thus, the secondary reference to Gordon and the tertiary reference to Lambert must disclose or suggest features (1)-(5) which the Examiner has acknowledged are missing from Jones.

On page 5, lines 3-4 of the Office Action, the Examiner states that "[t]he Gordon reference ***only*** used (sic) to show ethylene oxide gas sterilization of catheters." (Emphasis added) Similarly, on page 6, lines 1-2 of the Office Action, the Examiner repeats that "[t]he Gordon et al. reference used (sic) to show that ethylene oxide sterilization is known. The Gordon et al. reference is not used for the laminate structure."

Therefore, based on the Examiner's own admission, Gordon at best allegedly either discloses or suggests features (1), (4) and (5) which the Examiner stated are missing from the primary reference to Jones. Thus, after the combination of Jones and Gordon, items (2) and (3) are still missing.

The tertiary reference to Lambert is cited for its disclosure of a hydrophilic coated catheter. As such, Lambert does not overcome the failure of the combination of Jones and Gordon to disclose or suggest items (2) and (3).

Based on the Examiner's own representations regarding the cited prior art, Applicants submit that the combination of Jones, Gordon and Lambert does not suggest or result in the claimed invention. Rather, the combination of references allegedly suggests the use of a laminate as a barrier to ethylene oxide gas and a hydrophilic coated catheter. There is no suggestion of either feature (2) or (3), i.e., a package containing a medical instrument having a hydrophilic outer surface coating or a sealed container containing a sterile wetting fluid for wetting the hydrophilic coating of the instrument.

Once again, the Examiner has expressly stated that the Gordon reference is cited solely for its disclosure of the use of ethylene oxide as a sterilization gas. If, however, the Examiner also relies on Gordon for a suggestion of features (2) and (3), then the claimed invention is distinguishable over the claimed invention because the claimed invention does not use a lubricant-containing pouch formed from a gas impermeable material such as a metal or aluminum foil as disclosed and required by Gordon (col. 2, lines 45-50).

For all of the foregoing reasons, the combination of references does not suggest or result in the claimed invention and withdrawal of the §103 rejection is requested.

II. The combination of references is based on impermissible hindsight.

Applicants respectfully submit that the Examiner must look at the claimed invention from the perspective of an ordinary practitioner who is confronted with this problem: how to sterilize a newly developed medical product with ethylene oxide gas.

The newly developed medical product is an assembly comprising a medical instrument having a hydrophilic surface coating, and a container containing a pre-sterilized wetting fluid for wetting the hydrophilic coating. The ordinary practitioner would know that ethylene oxide residues will contaminate the wetting fluid and thereby render the wetting fluid unusable. Therefore, the ordinary practitioner would search for sterilization methods which allow the ethylene oxide to reach the medical instrument, and which prevent the gas from penetrating the container and contaminating the wetting fluid.

In the absence of impermissible hindsight, Applicants submit that the ordinary practitioner would not be motivated to combine Jones, Gordon, and Lambert to arrive at a solution as represented by the claimed invention.

A. Jones

In search of sterilization methods using ethylene oxide to sterilize the new medical instrument package, the ordinary practitioner would first review known methods of sterilizing medical packages.

As already acknowledged by the Examiner, Jones does not disclose or suggest a medical package formed from a silicon dioxide-containing laminate. Jones also does not suggest a method of using the disclosed laminate as a barrier against ethylene oxide. Accordingly, Applicants submit that the ordinary practitioner would not use Jones as a starting point for a method of using the prior art laminate in medical applications as a barrier material against ethylene oxide gas. In this regard, Applicants also refer to their remarks of record in the Amendment filed April 1, 2003.

B. Gordon

The secondary reference to Gordon discloses a catheter package which is sterilized using ethylene oxide gas. The catheter package contains a pouch of a lubricious material which is located adjacent to the tip of the catheter (Abstract). The pouch is formed from an aluminum foil or metal-containing barrier material (col. 2, lines 45-50). Therefore, at first glance, Gordon appears to be more directly related to Applicants' problem regarding the sterilization of a newly developed medical product with ethylene oxide gas.

As such, the ordinary practitioner would have reason to follow Gordon's use of an aluminum foil or metal-containing barrier material to safeguard the lubricant during sterilization of the medical instrument using ethylene oxide. There is no suggestion by Gordon that a barrier material other than aluminum foil or a metal could be used to protect the lubricant from ethylene oxide.

However, the Examiner indicates that Gordon is not used for the laminate structure in asserting the obviousness rejection. For the reasons given in Section I, above, the Examiner cannot rely solely on Gordon's disclosure of ethylene oxide as a sterilization gas and disregard Gordon's requirement that the lubricant-containing pouch contain a metal or aluminum foil as the gas impermeable material.

C. Lambert

The Examiner acknowledges that neither Jones nor Gordon disclose medical instruments having a hydrophilic coating. Therefore, the Examiner relies upon the tertiary reference to Lambert for an alleged disclosure that it is known to precoat catheters with a hydrophilic outer surface. However, Lambert does not disclose or suggest that a hydrophilic coating is stable under sterilizing conditions, and in particular in the presence of ethylene oxide gas. Lambert does not give any guidance on the stability of the hydrophilic coating under such conditions. Consequently, one of ordinary skill would have no basis for knowing whether the hydrophilic coating would be unaffected, or significantly deteriorated, in the presence of such an aggressive substance.

In fact, there is at least a strong suggestion that sterilization of the polymer surface is not necessary. In this regard, Lambert discloses that the hydrophilic coating can bind to elemental

iodine to form a hydrophilic and antibacterial coating. Catheters having such iodine-containing coatings can be inserted into the body for relatively long periods of time (col. 3, lines 50-57). Therefore, since such a coating has antibacterial properties, there is at least a suggestion that a separate sterilization step is not necessary. Accordingly, one of ordinary skill would not be motivated to use this hydrophilic coating, which apparently does not require sterilization, with ethylene oxide sterilization as disclosed by Gordon. As such, there is no motivation to combine Lambert with either Jones or Gordon.

For the reasons provided above, and for Applicants' remarks of record, the cited combination of references is possible only with impermissible hindsight. The ordinary practitioner would not be motivated to combine Jones, Gordon, and Lambert to solve the problem of sterilizing the newly developed medical assembly with ethylene oxide gas. Accordingly, withdrawal of the rejection of claims 1-10 under 35 U.S.C. § 103(a) is respectfully requested.

U.S. Patents 5,725,958; and 5,135,501 have been made of record but not relied upon for a prior art rejection. Applicants submit that none of these publications disclose or suggest the claimed invention.

CONCLUSION

Upon entry of this communication, claims 1-10 remain pending. Applicants respectfully submit that claims 1-10 are in condition for allowance, which action is earnestly solicited. Authorization is hereby given to charge any fee which may be due in connection with this communication to Deposit Account 23-1703.

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Respectfully submitted,

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